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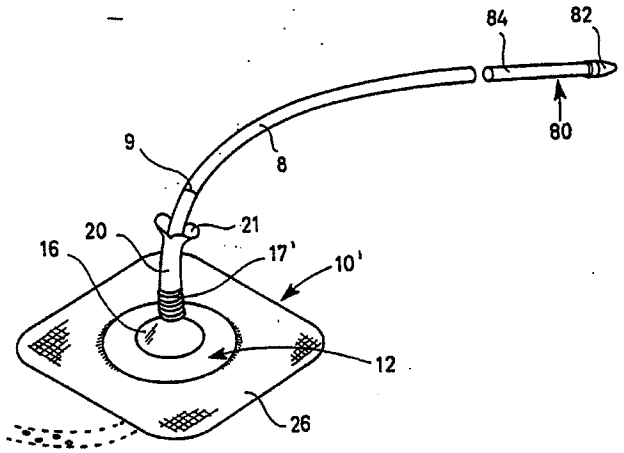

(57) Abstract

A drainage tube assembly comprises a drainage tube (8) and a device (10') for fixating the drainage tube relative to a skin surface part of a patient or person. The device (10') comprises a support component (12) including a flange part and a tubular part (17') which are integrally connected through a conical part (16). The tubular part (17') has a through-going passage for receiving the drainage tube (8), and the flange part has a surface part to be arranged in facial contact with the skin surface part of the patient or person in question. The device (10') further comprises a plaster component (26) including a support foil having opposite first and second side surfaces, which first side surface is provided with an adhesive layer for adhering to the flange component of the support component (12) and to the skin surface part of the patient or person in question. The device (10') also comprises a locking component (20) for locking the drainage tube (8) relative to the tubular part (17') of the support component (12). The drainage tube (8) is of an elongated tubular configuration and is provided with a positioning indication (9).

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A device for fixating a drainage tube, and a drainage tube assembly.

The present invention generally relates to the technique of applying and fixating a drainage tube relative to a skin surface part of a patient or person, and more precisely a device for fixating a drainage tube relative to a skin surface part of a patient or person.

It is a well-known technique to enter a drainage tube through the skin of a patient or person in order to drain liquid from a cavity within the patient or person, e.g. after a surgical operation. In certain applications, the drainage tube is also used for creating a vacuum within the cavity which is drained by means of the drainage tube. An example of such an application is the treatment of a collapsed lung, in which application the cavity of the thorax of the patient in question is evacuated through a pleural drainage tube in order to cause an adhesion of the pulmonary pleura of the patient to the costal pleura of the patient. In all applications of drainage tubes, there exists a risk that the drainage tube is blocked as the drainage tube is bent, or kinks of the drainage tube are produced. Provided the drainage tube is to be vented for creating a vacuum within the cavity which is vented through the drainage tube, a further problem exists in creating a reliable and lasting sealing of the entrance of the drainage tube through the skin of the patient, and further an overall desire of rendering it possible to create a sealing and a fixation of the drainage tube in a swift and reliable manner. Hitherto, the drainage tube, such as a pleural drainage tube which is used for venting the cavity of the thorax of the patient, the lung of whom has collapsed, has been fixated and sealed in a manual operation in which the medical doctor who applies the pleural drainage tube arranges one or more vaseline-impregnated wads round the pleural drainage tube at the entrance of the pleural drainage tube through the skin of the patient and compresses the vaseline-impregnated wads in order to create a sealing at the entrance. Thereupon, the vaseline-impregnated wads and the pleural drainage tube as well are fixated by means of plaster.

The technique of applying and fixating a drainage tube, in particular a venting drainage tube, such as a pleural drainage tube, is a complex and time-consuming operation which requires skill and which further often turns out to be inadequate and inappropriate as the sealing of the

entrance of the pleural drainage tube through the skin of the patient in question leaks, causing great harm to the patient.

An object of the present invention is to provide a device for fixating a drainage tube, which device to any substantial extent eliminates the risk that the drainage tube is bent at the entrance of the skin of the patient in question and further to any substantial extent eliminates the risk of creation of kinks of the drainage tube.

A particular advantage of the device according to the present invention lies in that a single unitary structure is provided which renders it possible, in a single and easily performable operation, to create a fixation of the drainage tube and also create a sealing of the entrance of the drainage tube through the skin of the patient.

A particular feature of the device according to the present invention lies in that the device according to the present invention constitutes a disposable unitary strucure which has been presterilized and simply is applied as a plaster structure to the skin of the patient after the device has, so to speak, been threaded on the drainage tube and is shifted along the drainage tube as a single unitary structure.

The above object, the above advantage, and the above feature together with numerous other objects, advantages, and features which will be evident from the below detailed description of preferred embodiments of the device according to the present invention are obtained by means of a device for fixating a drainage tube relative to a skin surface part of a patient or person, comprising in accordance with the present invention:

a support component including a flange part and a tubular part, said flange part and said tubular part being integrally connected, said tubular part having a through-going passage for receiving said drainage tube, and said flange part having a surface part to be arranged in facial contact with said skin surface part,

a plaster component including a support foil having opposite first and second side surfaces, said first side surface being provided with an adhesive layer, said plaster component being adhered to said flange part of said support component through a part of said adhesive layer, said plaster component having an exposed part of said adhesive layer to be arranged in contact with said skin surface part so as to fixate said surface part of said flange part relative to said skin surface part, and

a locking component for locking said drainage tube relative to said

tubular part of said support component.

The support component of the device according to the present invention provides, on the one hand, a support of the entrance of the drainage tube through the skin of the patient, which entrance is prevented from creating bends or kinks of the drainage tube due to the tubular part which receives the drainage tube and provides, on the other hand, a reliable fixation of the drainage tube due to the provision of the flange part which is arranged in facial contact with the skin surface part of the patient and fixated relative to the skin surface part by means of the plaster component. For preventing that the drainage tube be moved or shifted relative to the device according to the present invention, the drainage tube is locked to the tubular part of the support component by means of the locking component of the device.

In order to prevent that the adhesive layer of the plaster component be ruined prior to use, the exposed part of the adhesive layer of the plaster component is preferably covered by means of a cover sheet, which is removed prior to use.

In order to provide an even more reliable fixation of the device according to the present invention, and consequently of the drainage tube relative to the skin surface part of the patient in question, the surface part of the flange part of the support component may be provided with an adhesive layer for adhering to the skin surface part of the patient or person. Preferably, the adhesive layer of the flange part of the support component is a biologically compatible glue layer, such as a hydro-colloid layer which is glued to the surface part of the flange part by means of e.g. an adhesive layer, a glue or the like.

Provided the device according to the present invention is provided with an adhesive layer at the surface part of the flange part of the support component, the cover sheet preferably also covers the adhesive layer of the surface part of the flange part.

The flange part of the support component may be of a rectangular or a curved geometrical configuration or any alternative appropriate configuration fulfilling the basic object of the present invention. Thus, the flange part of the support component may e.g. be of a plane configuration or of an overall conical configuration or any alternative appropriate configuration. The flange part of the support component, however, is preferably of an annular configuration which flange part encircles the tubular part which consequently constitutes a part protruding from an

encircling flange part.

The flange part and the tubular part are integrally connected, either directly or in accordance with the presently preferred embodiment of the device according to the present invention through a conical part which serves two purposes, viz. the purpose of creating means for maintaining the flange part and the tubular part of the support component in appropriate distance from the entrance of the drainage tube through the skin surface part of the patient, and consequently the purpose of preventing that the support component is arranged in direct contact with the tissue at the entrance of the drainage tube through the skin surface part of the patient or person, and the additional purpose of providing a space below the conical part of the support component after the device is applied to the skin surface part of the patient or person, in which space a sealing material is preferably received or arranged. Thus, the device according to the present invention preferably comprises a plug or sponge of a biologically non-aggressive and wound-care or wound-treatment compatible material, which plug or sponge has a through-going hole and is arranged within the conical part of the support component, serving the purpose of filling out and sealing the above described space below the conical part of the support component.

The plaster component of the device according to the present invention may be of any appropriate configuration, serving the purpose of providing a reliable and lasting fixation of the flange part of the support component relative to the skin surface part of the patient. As the flange component of the support component preferably is constituted by an annular flange component encircling the tubular part, the plaster component preferably has an aperture through which the tubular part of the support component protrudes.

The present invention also relates to a drainage tube assembly comprising a drainage tube and a device for fixating the drainage tube relative to a skin surface part of a patient or person, the device comprising:

a support component including a flange part and a tubular part, said flange part and said tubular part being integrally connected, said tubular part having a through-going passage for receiving said drainage tube, and said flange part having a surface part to be arranged in facial contact with said skin surface part,

a plaster component including a support foil having opposite first

and second side surfaces, said first side surface being provided with an adhesive layer, said plaster component being adhered to said flange part of said support component through a part of said adhesive layer, said plaster component having an exposed part of said adhesive layer to be arranged in contact with said skin surface part so as to fixate said surface part of said flange part relative to said skin surface part, and

a locking component for locking said drainage tube relative to said tubular part of said support component.

The drainage tube assembly according to the present invention consequently comprises a device according to the present invention and further a drainage tube which is of an elongated tubular configuration, i.e. a conventional configuration per se, however, further being provided with a positioning indication allowing an exact positioning of the drainage tube relative to the patient as the positioning indication simply indicates how far the drainage tube is to be entered into the patient in question, particularly into the cavity of the thorax of the patient in question, for properly and correctly positioning the drainage tube. It is to be realized that in case the drainage tube is not correctly entered and positioned relative to the patient, great harm may in some instances be incurred to the patient as e.g. the vacuum which is created within the cavity in the treatment of e.g. a collapsed lung may result in extremely dangerous and harmful subcutaneous swelling of large areas of the chest and face of the patient, provided some air unintentionally is subcutaneously vented.

The drainage tube assembly according to the present invention preferably comprises a device for fixating the drainage tube relative to the skin surface part of the patient or person in question which device according to the teachings of the present invention may comprise any of the features and characteristics discussed above. According to the presently preferred embodiment of the drainage tube assembly according to the present invention, the assembly further comprises a removable plug body for sealing an outer end of the drainage tube and for supporting the outer end of the drainage tube during the introduction of the outer end of the drainage tube through the through-going passage of the tubular part of the support component. By the provision of the removable plug body, the process of introducing the outer free end of the drainage tube through the through-going passage of the tubular part of the support component is made easier as any tendency of the outer

free end of the drainage tube to collapse and consequently stick within the through-going passage of the tubular part of the support component is to a great extent eliminated. Also the possibility of unintentionally venting the cavity of e.g. the thorax of the patient or person in question through the drainage tube during the process of introducing the outer free end of the drainage tube through the through-going passage of the tubular part of the support component and during the process of applying and fixating the device to the skin surface part of the patient or person in question is to a great extent eliminated. Thus, is it to be realized that unless the removable plug body for sealing the outer free end of the drainage tube is used for its intentional purpose, the drainage tube has to be locked by means of locking instruments such as a conventional forceps usually used during surgery.

In accordance with a further preferred embodiment of the assembly according to the present invention, the plug body is fitted into the outer end of the drainage tube in a tight fit and presents a blunt end body part protruding from the outer end of the drainage tube. In accordance with the above described preferred embodiment of the assembly according to the present invention, the removably plug body constitutes a separate component which is easily fitted into the outer free end of the drainage tube and maintained in position relative to the drainage tube through the tight fit established between the plug body and the drainage tube and also easily introduced into the through-going passage of the tubular part of the support component of the device as the plug body presents a blunt end body part.

The present invention will now be further described with reference to the drawings, in which

Fig. 1 is a schematical view of the application of a first embodiment of a drainage tube assembly comprising a device according to the present invention for fixating a drainage tube, and more precisely a pleural drainage tube at the thorax of a patient,

Figs. 2 and 3 are schematical views illustrating the technique of applying the first embodiment of a drainage tube assembly comprising the device shown in Fig. 1 at the thorax of a patient for fixating the pleural drainage tube relative to the thorax of the patient and further for sealing the entrance of the pleural drainage tube into the thorax of the patient,

Fig. 4 is a partly sectional view of the first embodiment of the

drainage tube assembly comprising the device according to the present invention shown in Figs. 1-3 applied to a skin surface part of the thorax of a patient and fixating the pleural drainage tube and further sealing the entrance of the pleural drainage tube into the thorax,

Fig. 5 is an exploded view of the first embodiment of the device of the drainage tube assembly according to the present invention, illustrating the structure of the device,

Fig. 6 is a partly sectional view similar to the view of Fig. 4, illustrating a second embodiment of the drainage tube assembly according to the present invention,

Fig. 7 is an exploded view similar to the view of Fig. 5, illustrating the structure of the second embodiment of the device of the drainage tube assembly according to the present invention also shown in Fig. 6, and

Figs. 8 and 9 are schematic views similar to the views of Figs. 2 and 3 illustrating a further embodiment of the drainage tube assembly comprising a device similar to the device shown in Figs. 1, 2, 3, 4 and 5, and the pleural drainage tube shown in Figs. 1-6 and further comprising a blunt end sealing plug body.

In Figs. 1-5, a first embodiment of a drainage tube assembly comprising a drainage tube and a device for fixating the drainage tube, and specifically a pleural drainage tube, is shown. The first embodiment shown in Figs. 1-5, and to be described in greater details below, basically serves three main purposes, viz. the purpose of fixating the pleural drainage tube relative to the thorax of the patient without creating kinks or bends of the pleural drainage tube, the purpose of sealing the entrance of the pleural drainage tube into the thorax of the patient in order to render it possible to create a vacuum within the cavity of the thorax of the patient so as to cause an adhesion of the pulmonary pleura of the patient to the costal pleura of the patient, and the purpose of correctly entering and positioning the drainage tube relative to the thorax of the patient so as to eliminate, to any substantial extent, the risk that the drainage tube is, on the one hand, entered too far into the thorax which might cause injuries within the thorax and, on the other hand, entered too short a distance into the thorax which might cause hazardous transcutaneous swelling of the thorax, and even the face of the patient.

The first embodiment of the drainage tube assembly according to the

present invention further serves the overall purpose of providing a drainage tube assembly and a device which render it extremely simple and far less complicated than hitherto to fixate and seal a pleural drainage tube to the thorax of a patient, further providing a reliable and lasting fixation and sealing.

In Fig. 5, the structure of the first embodiment of the device according to the present invention is shown. The first embodiment of the device is in its entirety designated the reference numeral 10 and centrally comprises a flange component 12 comprising an annular flange part 14, a conical part 16, and a tubular part 17 which is provided with a central through-going hole. The component 12 is a component which is integrally cast from a biologically acceptable plastic material, e.g. polyethylene, polypropylene or the like. The tubular part 17 is at its outer circumferential surface provided with a glue layer 18 serving the purpose of fixating and sealing a hose component 20 relative to the tubular part 17 of the flange component 12. The hose component 20 is, as is evident from Fig. 5, provided with two outwardly protruding gripping tags, the purpose of which will be evident from the below detailed description of the technique of applying the first embodiment 10 of the device according to the present invention to the thorax of a patient. One of the gripping tags of the hose component 20 is designated the reference numeral 21.

The flange component 12 is at its lower side surface, i.e. opposite to the side surface from which the conical part 16 and the tubular part 17 protrude, provided with an annular adhesive tape 22 which is provided with adhesive layers at opposite side surfaces and which serves the purpose of fixating a biologically compatible or acceptable glue material constituted by an annular hydro-colloid component 24 relative to the annular flange part 14 of the flange component 12. The lower side surface of the annular hydro-colloid component 24, i.e. the side surface of the component 24 opposite to the side surface which is adhered to the lower side surface of the annular flange part 14 of the flange component 12 by means of the annular adhesive tape 22 is to be arranged in contact with and adhered to a skin surface part of the patient to whom the device 10 is applied.

For further fixating the device 10 relative to the skin surface part of the patient, the device 10 is provided with a plaster component 26 which is provided with a central aperture 27. The plaster component

26 is arranged on top of the annular flange component 14 covering the upper side surfaces of the annular flange part 14 and the conical part 16 of the flange component 12 and further protruding beyond the outer rim of the annular flange part 14 of the flange component 12. The plaster component 26 is, as will be understood, provided with an adhesive layer at its lower side surface, by means of which the plaster component 26 adheres to the flange component 12 and further to the skin surface part of the patient to whom the device 10 is applied.

For protecting the adhesive layer of the plaster component 26 and further the adhesive layer of the annular hydro-colloid component 24, two cover sheets 34 and 36 are provided, covering the exposed adhesive layer of the plaster component 26 and the exposed lower side surface of the annular hydro-colloid component 24. The cover sheets 34 and 36 are of substantially identical configuration and adjoin one another along a line of separation 38 extending substantially diametrically across the plaster component 26. The adjoined cover sheets 34 and 36 are centrally provided with an aperture 35 through which a sealing component constituted by two foam plugs 30 and 32 is exposed. The foam plugs 30 and 32 are provided with through-going hols and are glued together so as to constitute a single integral foam plug which is further glued to the lower side surface of the conical part 16 of the flange component 12. The foam plugs 30 and 32 differ from one another in that the foam plug 32 to be arranged in direct contact with the tissue of the entrance of the pleural drainage tube through the thorax is impregnated with vaseline in order to provide a sealing round this entrance of the drainage tube through the tissue of the patient and round the drainage tube, i.e. relative to the incision, the drainage tube and the surrounding skin surface and tissue, and to prevent that the foam plug 32 adjoins the tissue of the entrance and further provides a biologically acceptable contact between the foam plug 32 and the tissue.

The aperture 35 of the cover sheets 34 and 36, and further the foam plugs 30 and 32, are covered by a cover 40 which is glued to the lower, exposed side surfaces of the cover sheets 34 and 36 by means of adhesive tape or adhesive glue.

The device 10 is, as shown in Fig. 1, adapted to be arranged at the thorax of a patient 2, the sternum of whom is designated the reference numeral 4, and one rib of whom is designated the reference numeral 6. A pleural drainage tube 8 is introduced into the cavity between the costal

pleura and the pulmonary pleura as the lung of the patient has collapsed due to e.g. perforation, through a costal interspace and is fixated and sealed relative to the thorax of the patient 2 by means of the device 10. The pleural drainage tube 8 is introduced to a specific distance or position relative to the thorax of the patient in question, which distance or position is indicated to the person, such as the doctor or nurse, fixating the pleural drainage tube by means of a positioning indication constituted by a circumferential mark 9 of the pleural drainage tube 8, which circumferential mark informs the doctor or nurse to what distance or depth the pleural drainage tube has been introduced. Preferably, the pleural drainage tube is introduced to a certain depth so as to conceal the circumferential mark 9 within the thorax of the patient 2. Alternatively, the circumferential mark 9 may be positioned a short distance from the device 10, informing the doctor or nurse that the pleural drainage tube or the outermost end of the pleural drainage tube has been introduced into the thorax of the patient to a certain depth within the thorax of the patient.

The device 10 is applied in accordance with a technique which is disclosed in Figs. 2 and 3. After the pleural drainage tube 8 has been introduced into the above described cavity of the thorax of the patient to the intentional position relative thereto as indicated by the positioning indication or circumferential mark 9, and optionally fixated relative to the skin of the patient by means of short segments of thread, as is illustrated in the lower right-hand part of Fig. 2, the cover 40 is removed, uncovering the vaseline-impregnated foam plug 32 through the aperture 35 of the cover sheets 34 and 36.

The outer end of the pleural drainage tube 8 is introduced through the trough-going holes of the foam plugs 30 and 32 and further through the through-going hole of the tubular part 17 of the flange component 12, as is illustrated in Fig. 2, which through-going holes are in registration. Thereupon, the cover sheets 34 and 36 are removed, exposing the adhesive layer of the plaster component 26, and further the outer or lower exposed side surface of the annular hydro-colloid component 24. The device 10 is as a unitary structure shifted along the pleural drainage tube 8 and is brought into facial contact with the outer skin surface of the thorax of the patient.

The adhesive layer at the lower side surface of the plaster component 26 adheres to the skin surface part of the patient and the annular

hydro-colloid component 24 also adheres to the skin surface part of the patient. The annular hydro-colloid component 24 additionally serves the purpose of providing a seal between the lower side surface of the annular flange part 14 of the flange component 12 and an annular skin surface part of the patient, which skin surface part encircles the pleural drainage tube 8 and further the aperture of the skin through which the pleural drainage tube is entered into the cavity of the thorax.

The foam plugs 30 and 32 are substantially compressed and provide a filling-out of the cavity below the conical part 16 of the flange component 12 and providing a hermetical seal below the flange component 12, and consequently between the aperture of the skin through which the pleural drainage tube 8 is entered into the cavity of the thorax and the environment.

After the facial contact and adhesion between the plaster component 26 and further the annular hydro-colloid component 24 and the skin surface of the patient has been established, the hose 20 is shifted from its position shown in Figs. 2 and 5 in which the hose is turned inside down to its position shown in Fig. 1 in which the hose is pulled out and encircles a segment of the pleural drainage tube for hermetically sealing the interspace between the tubular part 17 of the flange component 12 and the pleural drainage tube 8 as one of the gripping tags 21 of the hose is gripped by a person, e.g. a medical doctor or nurse who applies the device 10 and who grips the gripping tag 21 by means of the thumb and the forefinger of his or her hand 3.

In Fig. 4, a partly sectional view illustrates the device 10 after the device has been applied as discussed above with reference to Figs. 2 and 3. Fig. 4 clearly illustrates the facial adhesive contact between the device 10 and the outer skin surface of the patient 2 through the plaster component 26 and further through the annular hydro-colloid component 24 which is glued or adhered to the lower side surface of the annular flange part 14 of the flange component 12 through the annular adhesive tape 22. The substantially compressed and deformed foam plugs 30 and 32 are also illustrated in Fig. 4, serving the purpose of providing, as discussed above, a hermetic seal and a wound-care or wound-treatment compatible fixation of the pleural drainage tube at the entrance of the pleural drainage tube through the aperture of the thorax. The fixation and sealing capability of the hose 20 is also clearly illustrated in Fig. 4 as the hose 20 is pulled out around the pleural drainage tube 8,

providing a tight fit round the pleural drainage tube 8. From Fig. 4, it is also evident in what way the flange component 12 supports the pleural drainage tube 8 at the entrance through the skin of the patient and prevents that bends or kinks of the pleural drainage tube 8 be created. Fig. 4 also illustrates the preferred positioning of the circumferential mark 9 concealed within the thorax of the patient, informing the doctor or nurse that the pleural drainage tube 8 has been introduced into the thorax of the patient in question to the correct depth or position.

Figs. 6 and 7 are views similar to the views of Figs. 4 and 5, respectively, illustrating a second or alternative embodiment according to the present invention, which embodiment is designated the reference numeral 50 in its entirety. The device 50 comprises a component 52 similar to the component 12 of the device 10 described above with reference to Figs. 1-5, which component 52 comprises a conical flange part 54 and an upwardly protruding tubular part 56 which is provided with a through-going hole and outer thread. The drainage tube, e.g. the pleural drainage tube 8 shown in Figs. 1-4 and 6, is fixated and sealed relative to the flange component 52 of the device 50 by means of an O-ring 58 and a cap 60 which is provided with a through-going hole and inner thread meshing with the outer thread of the tubular part 56. The O-ring 58 provides an O-ring sealing well-known in the art per se.

Similar to the plaster component 26 of the device 10, the device 50 is provided with a plaster component 62 which is also provided with a central aperture 63 serving the same purpose as the aperture 27 of the plaster component 26. The device 50 further comprises an annular component 64 which may constitute a sponge similar to the plug 32, or alternatively constitute a component similar to the annular hydro-colloid component 24. The component 64 may constitute a component which is glued or adhered to the lower side surface of the flange component 52, or alternatively constitute a separate component which is mounted in a separate application step on the drainage tube, such as the pleural drainage tube 8 shown in Fig. 6. Similar to the first embodiment 10 of the device according to the present invention described above with reference to Figs. 1-5, the second embodiment 50 shown in Fig. 7 comprises two cover sheets 66 and 68 which are adjoined along a line of separation 70.

In Fig. 6, a sectional view similar to the view of Fig. 4 is shown illustrating the second embodiment 50 of the device according to the present invention applied to a drainage tube, and more precisely the

pleural drainage tube 8. In Fig. 6, the component 64 constitutes a component similar to the component 22 shown in Fig. 4, i.e. an annular hydro-colloid component serving the purpose of providing an adhesion of the flange of the annular flange component 52 to the skin surface part of the patient 2, whereas a separate sponge or wound treatment component is provided, designated the reference numeral 72. Fig. 6 also illustrates the above described alternative positioning of the circumferential mark 9 a short distance from the device 50.

In Fig. 8, an alternative or modified embodiment of the device according to the present invention is shown designated the reference numeral 10′ in its entirety. The device 10′ is of a structure similar to the structure of the device 10 described above with reference to Fig. 1, 2, 3, 4 and 5, however, differing from the above described embodiment in that the cover sheets 34 and 36 are substituted by cover sheets 34′ and 36′ which are of a somewhat reduced size as compared to the size of the cover sheets 34 and 36, still covering the entire lower side surface of the plaster component 26 prior to the removal of the cover sheets. The embodiment 10′ also differs from the above described preferred embodiment 10 in that the flange component 12 comprises a tubular part 17′ of a folded structure allowing that the tubular part 17′ is bent without causing a collapse of the drainage tube 8 received within the tubular part 17′. In Fig. 8, the device 10′ of the drainage tube assembly is shown in the state in which the drainage tube 8 has been introduced through the tubular part 17′ of the device 10′ after the introduction of the pleural drainage tube 8 into the cavity of the thorax of the patient or person.

The drainage tube shown in Fig. 8 is provided with a further component constituting a removable plug body designated the reference numeral 80 in its entirety. The removably plug body 80 basically serves the main purpose of sealing the outer free end of the pleural drainage tube 8 during the process of fixating the pleural drainage tube relative to the thorax of the patient or person in question. Thus, the removable plug body 80 constitutes a sealing plug body as is evident from Fig. 9 which plug body comprises a blunt end part 82 protuding from the outer free end of the pleural drainage tube 8 as is shown in Fig. 8 and a conical part 84 defining an outer diameter allowing that the cylindrical part is received within the interior of the pleural drainage tube 8 at the outer free end thereof as shown in Fig. 8 in a tight fit providing a sealing

of the outer free end of the pleural drainage tube. The removable plug body 80 further serves the additional purpose of supporting the outer free end of the pleural drainage tube 8 and consequently preventing that the outer free end is collapsed during the process of introducing the outer free end of a pleural drainage tube through the tubular part 17' of the device 10' or provided the removable plug body 80 is used in connection with the above described first and second embodiments of the device introduced through the tubular part 17 of the first embodiment of the device 10 described above with reference to Figs. 1-4 or through the tubular part 56 of the second embodiment of the device 50 described above with reference to Fig. 6 and 7. The blunt end part 82 of the removable plug body 80 allows that the plug body 80 and consequently the pleural drainage tube 8 is easily introduced through the tubular part of the device for fixating the pleural drainage tube in accordance with the teachings of the present invention.

By the provision of the removable plug body 80, a conventional sealing mean suchs as a forceps may be elimiated. Provided the removable plug body 80 is not employed, the doctor or nurse applying the drainage tube and further the device for fixating the drainage tube relative to the thorax of the patient or person in question normally uses two forceps for preventing that the cavity into which the drainage tube is introduced is evacuated or vented unintentionally through the drainage tube which has to be kept sealed or closed during the processes of introducing the pleural drainage tube and of fixating the pleural drainage tube.

In Fig. 9, the device 10' is shown after the device has been applied to the skin surface part of the patient or person in question and further illustrates the removable plug body 80 after the removable plug body 80 has been removed from the drainage tube 8.

It is to be realized that the embodiments described above with reference to Figs. 1-9 may be modified in numerous ways and further combined so as to provide a device for fixating a drainage tube and optionally for sealing the drainage tube or the aperture of the skin surface part through which the drainage tube extends. Basically, the device comprises a flange component and a plaster component, whereas the other components described above, such as the hydro-colloid component, the sealing components constituted by the hose 20 or alternatively the meshing threads and the sealing O-ring 58 shown in Fig. 7 may be omitted or

alternatively substituted by any other appropriate sealing means such as wedge-shaped sealing means, adhesion tape or the like. Whereas the foam plugs 30 and 32 described above are preferably glued to the inner side surface of the conical part 16 of the flange component 12 and further glued together, so as to constitute a single integral component, the foam plugs 30 and 32 and any components similar to these plugs, such as the sponge 72 shown in Fig. 6, or alternatively the component 64, also shown in Fig. 6, may be fixed to an adjacent side surface of the flange component of the device, or alternatively constitute separate components to be arranged in a separate application step on the drainage tube which may constitute a pleural drainage tube or any alternative drainage tube which need to be sealed or, alternatively, need not be sealed.

Example

A prototype implementation of the presently preferred embodiment of the device according to the present invention shown in Figs. 1-5 and designated the reference numeral 10, was made from the following components.

The component 12 was cast from polyethylene. The outer diameter of the component 12 was 70 mm, the inner diameter of the annular flange part 14 of the component 12 was 35 mm. The thickness of the annular flange part 14 and the conical part 16 was 0.85 mm, and the wall thickness of the tubular part 17 was 1 mm. The inner diameter of the through-going hole of the tubular part 17 was 12 mm. The height of the conical part 16 was 8 mm, and the length of the tubular part 17 was 16 mm. The hose 20 was made from latex rubber of a thickness of 1.1 mm. The annular adhesive tape 22 was a 0.07 mm thick double-sided adhesive tape. The annular hydro-colloid component 24 had a thickness of 2.0 mm. The outer diameter of the components 22 and 24 were 70 mm and the through-going apertures of the annular components 22 and 24 had a diameter of 35 mm. The vaseline-impregnated foam plug 32 was made from polyurethane foam (16 kg/m^3) and had a height of 5 mm and an outer diameter of 30 mm. The foam plug 30 was also made from polyurethane foam (16 kg/m^3) and had a height of 7 mm and an outer diameter of 23 mm. The through-going holes of the plugs 30 and 32 were of a diameter of 10 mm. The plaster component 26 was of the material non-woven polyester (MICROTAPE®) and measured 120 mm x 120 mm. The diameter of the aperture 27 of the plaster component 26 had a diameter of 35 mm. The cover sheets 34 and 36 were

made from siliconized polyester and together measured 140 mm x 140 mm, providing a central aperture of a diameter of 35 mm. The cover 40 was cast from PVC.

The pleural drainage tube 8 was a Charrier 28-32 PVC tube of a length of 70 cm. The pleural drainage tube 8 was at its distal end provided with a total of eight holes. The marking 9 was constituted by a circumferential mark provided at a distance of 17 cm from the distal end of the pleural drainage tube 8.

List of reference numerals:

2	patient/skin surface
3	hand
4	sternum
6	rib
8	pleural drainage tube
9	mark
10	first embodiment of the device
10′	alternative embodiment of the device
12	flange component
14	annular flange part
16	conical part
17	tubular part
17′	folded tubular part
18	glue layer
20	hose component
21	gripping tag
22	annular adhesive tape
24	annular hydro-colloid component
26	plaster component
27	central aperture
30	foam plug
32	vaseline-impregnated foam plug
34	cover sheet
34′	cover sheet
35	aperture
36	cover sheet
36′	cover sheet
38	line of separation
40	cover
50	second embodiment of the device
52	flange component
54	conical part
56	tubular part
58	O-ring
60	cap component

62 plaster component
63 aperture
64 annular component
66 cover sheet
68 cover sheet
70 line of separation
72 sponge
80 removable plug body
82 blunt end part
84 cylindrical part

CLAIMS

1. A device for fixating a drainage tube relative to a skin surface part of a patient or person, comprising:

a support component including a flange part and a tubular part, said flange part and said tubular part being integrally connected, said tubular part having a through-going passage for receiving said drainage tube, and said flange part having a surface part to be arranged in facial contact with said skin surface part,

a plaster component including a support foil having opposite first and second side surfaces, said first side surface being provided with an adhesive layer, said plaster component being adhered to said flange part of said support component through a part of said adhesive layer, said plaster component having an exposed part of said adhesive layer to be arranged in contact with said skin surface part so as to fixate said surface part of said flange part relative to said skin surface part, and

a locking component for locking said drainage tube relative to said tubular part of said support component.

2. The device according to Claim 1, further comprising a cover sheet covering said exposed part of said adhesive layer of said plaster component.

3. The device according to any of the Claims 1 or 2, said surface part of said flange part of said support component being provided with an adhesive layer for adhering to said skin surface part.

4. The device according to Claim 3, said adhesive layer of said flange part being a biologically compatible glue layer.

5. The device according to Claim 4, said adhesive layer of said flange part being constituted by a hydro-colloid layer which is glued to said surface part of said flange part.

6. The device according to Claim 2 and any of the Claims 3-5, said cover sheet further covering said adhesive layer of said surface part of said flange part.

7. The device according to any of the Claims 1-6, said flange part of said support component being of an annular configuration and said flange part encircling said tubular part.

8. The device according to Claim 7, said annular flange part and said tubular part being integrally connected through a conical part of said support component.

9. The device according to Claim 8, further comprising a plug or sponge of a biologically non-aggressive and wound-treatment compatible material, said plug or sponge having a through-going hole and being arranged within said conical part of said support component.

10. The device according to any of the Claims 1-9, said plaster component having an aperture through which said tubular part of said support component protrudes.

11. A drainage tube assembly comprising a drainage tube and a device for fixating said drainage tube relative to a skin surface part of a patient or person, said device comprising:

a support component including a flange part and a tubular part, said flange part and said tubular part being integrally connected, said tubular part having a through-going passage for receiving said drainage tube, and said flange part having a surface part to be arranged in facial contact with said skin surface part,

a plaster component including a support foil having opposite first and second side surfaces, said first side surface being provided with an adhesive layer, said plaster component being adhered to said flange part of said support component through a part of said adhesive layer, said plaster component having an exposed part of said adhesive layer to be arranged in contact with said skin surface part so as to fixate said surface part of said flange part relative to said skin surface part, and

a locking component for locking said drainage tube relative to said tubular part of said support component, and

said drainage tube being of an elongated tubular configuration and being provided with a positioning indication.

12. The assembly according to Claim 11, said device further comprising any of the characteristics according to any of the claims 2-10.

13. The assembly according to any of the Claims 11 or 12, further comprising a removable plug body for sealing an outer end of said drainage tube and for supporting said outer end of said drainage tube during introduction of said outer end of said drainage tube through said through-going passage of said tubular part of said support component.

14. The assembly according to Claim 13, said plug body being fitted into said outer end of said drainage tube in a tight fit and presenting a blunt end body part protruding from said outer end of said drainage tube.

Fig. 1

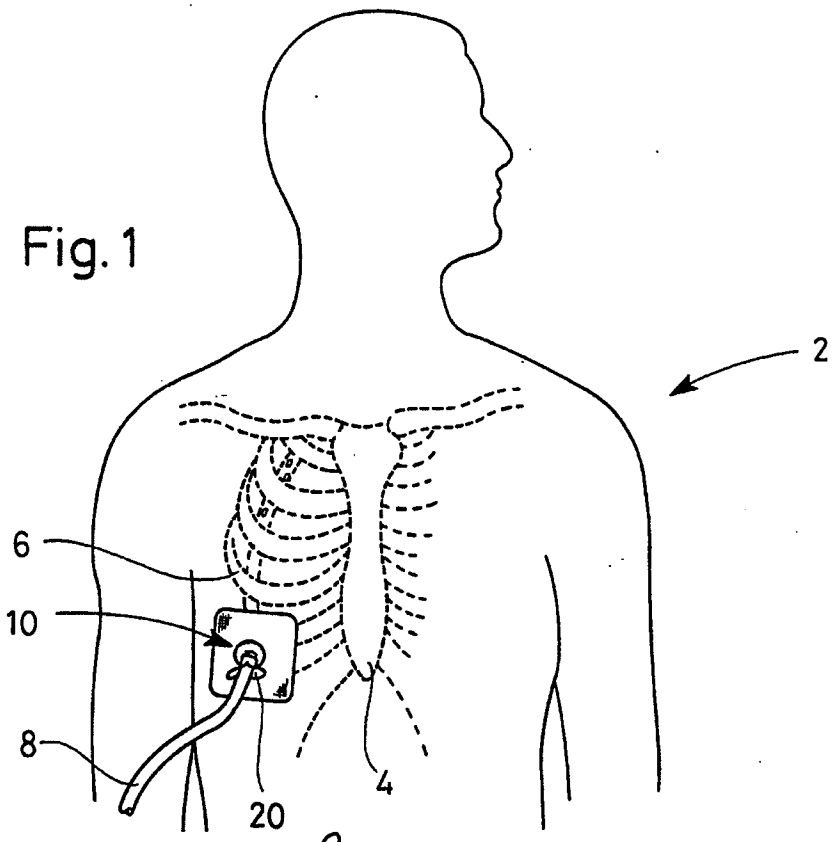


Fig. 2

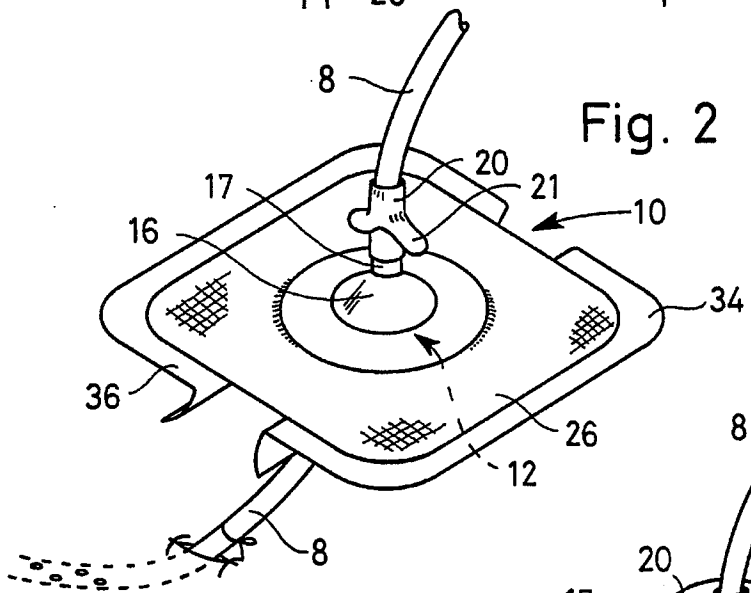
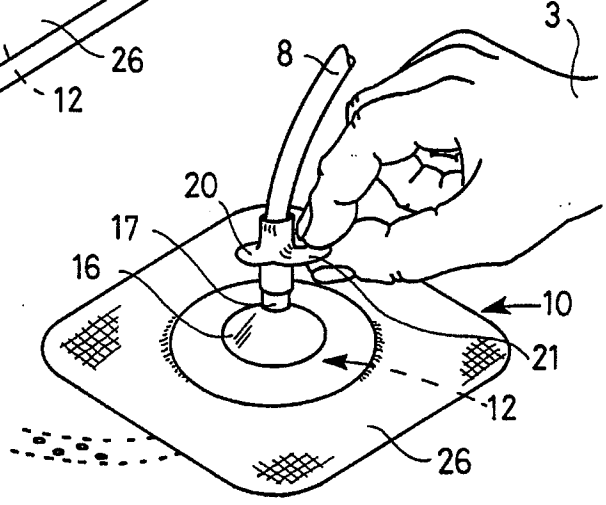


Fig. 3



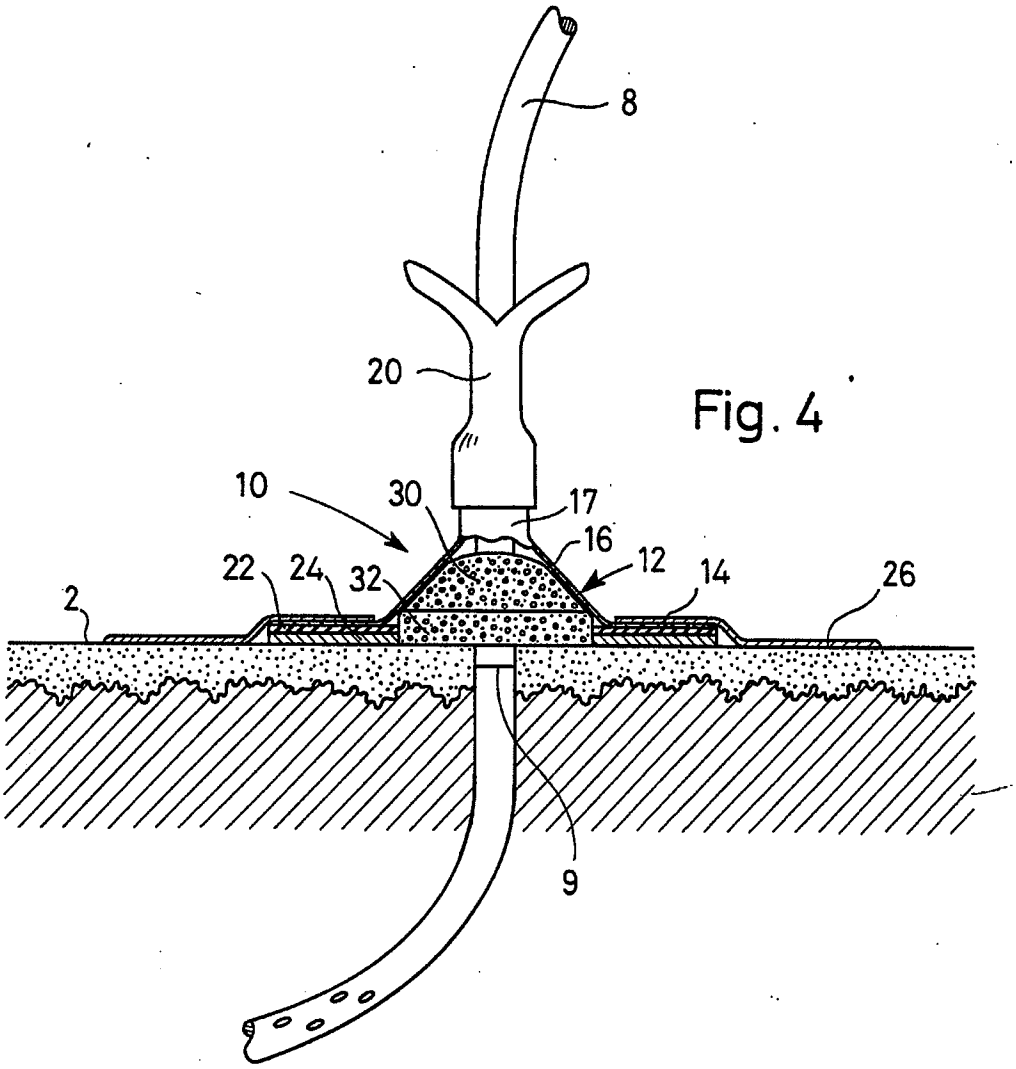


Fig. 4

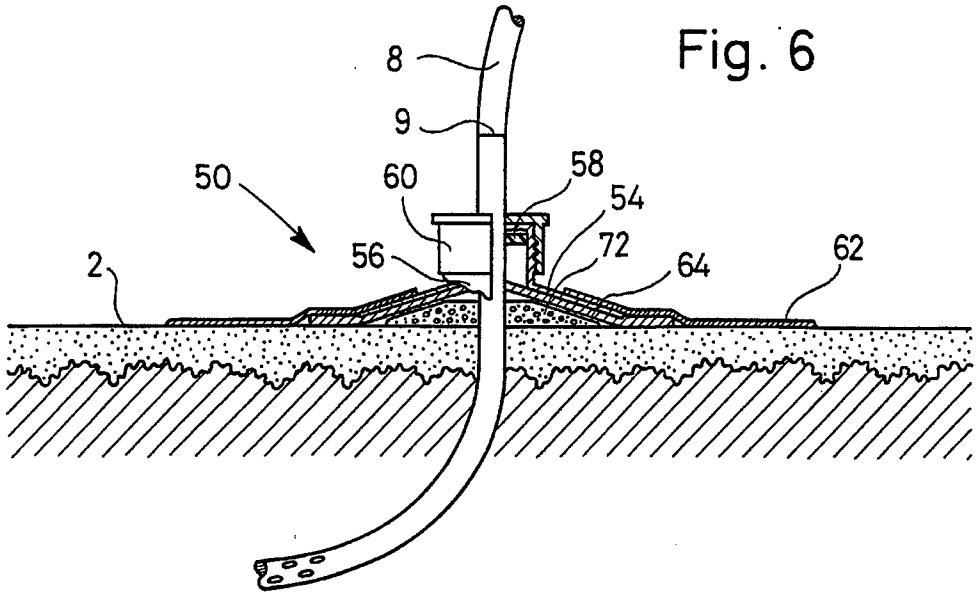


Fig. 6

Fig. 5

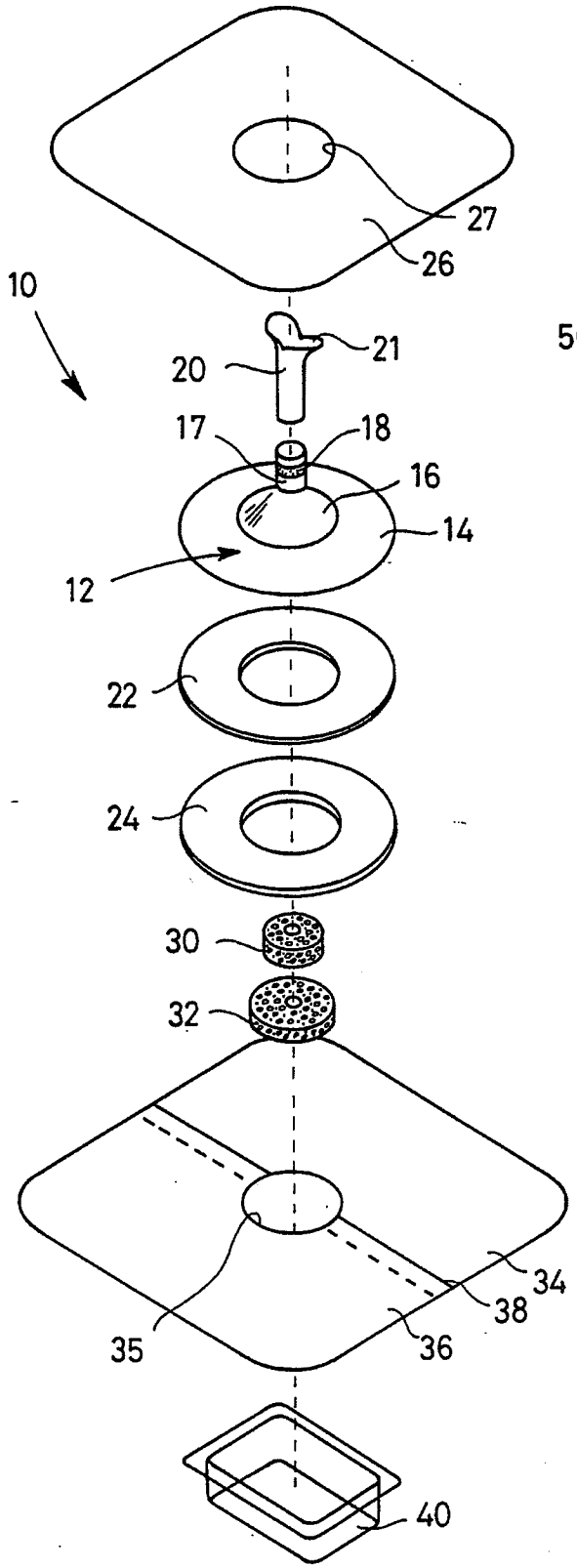

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Fig. 7

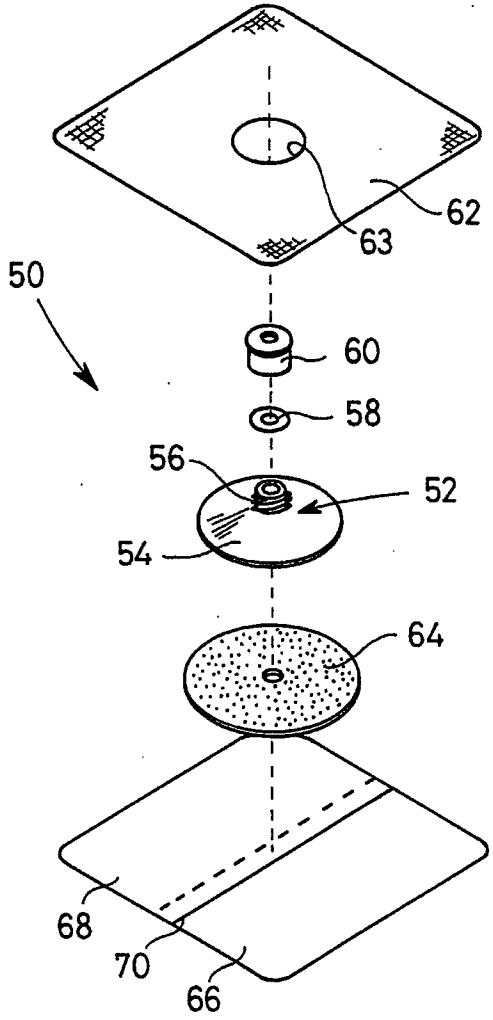
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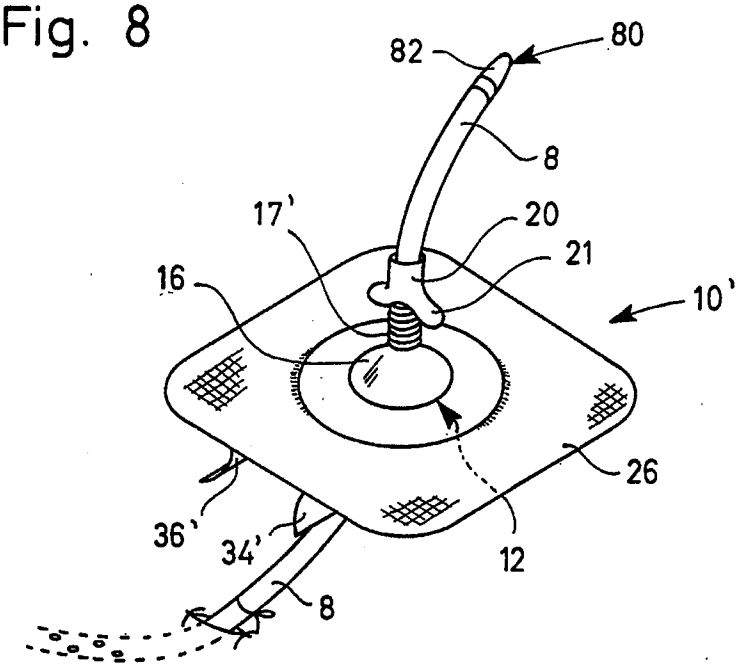
Fig. 8



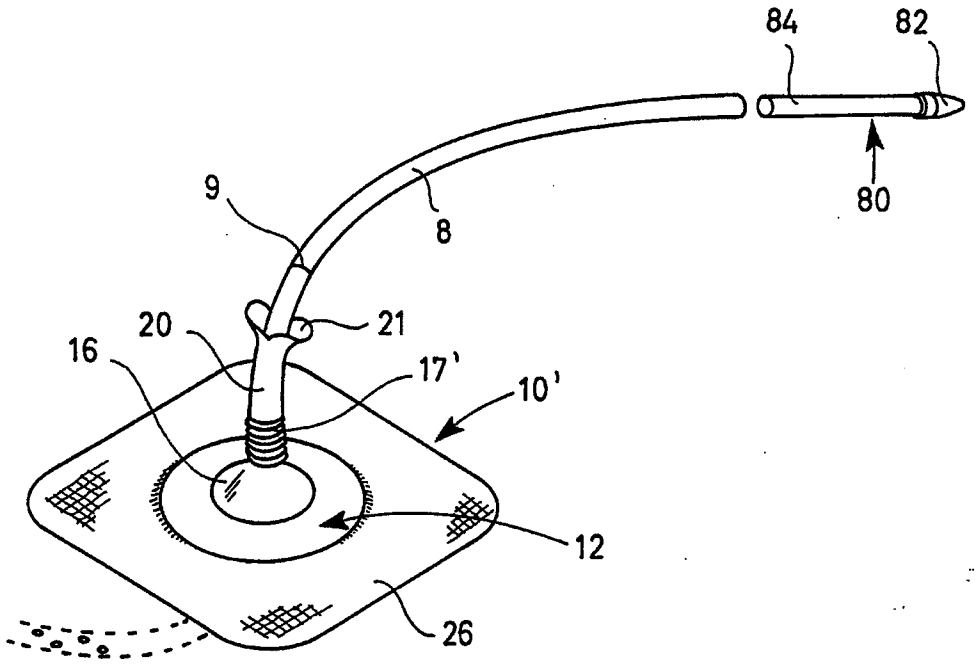


Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 93/00203

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61M 25/02, A61M 27/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC5: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	SE, B, 435134 (THE KENDALL COMPANY), 10 Sept 1984 (10.09.84) --	1-4,6-8, 10-12
Y	GB, A, 2191407 (HOLLISTER INCORPORATED), 16 December 1987 (16.12.87), see especially the adhesive-coated surrounding layer 18 and the release sheets 20 --	1-4,6-8, 10-12
Y	US, A, 2898917 (F.J. WALLACE), 11 August 1959 (11.08.59) --	1-4,6-8, 10-12
Y	US, A, 3683911 (MCCORMICK), 15 August 1972 (15.08.72) --	1-4,6-8, 10-12

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 Sept 1993	20 -09- 1993
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Vingård Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 93/00203

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4419094 (PATEL), 6 December 1983 (06.12.83)	1-4,6-8, 10-12
Y	US, A, 4767411 (EDMUNDS), 30 August 1988 (30.08.88)	1-4,6-8, 10-12

INTERNATIONAL SEARCH REPORT

Information on patent family members

26/08/93

International application No.
PCT/DK 93/00203

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SE-B- 435134	10/09/84	AU-B-	515294	26/03/81
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		BE-A-	866583	14/08/78
		CA-A-	1113822	08/12/81
		DE-A-	2817232	02/11/78
		FR-A,B-	2388567	24/11/78
		GB-A-	1560458	06/02/80
		JP-A-	53136393	28/11/78
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		US-A-	4205691	03/06/80
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		JP-C-	1683152	31/07/92
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		NL-A-	8701373	04/01/88
		US-A-	4699616	13/10/87
US-A- 2898917	11/08/59	NONE		
US-A- 3683911	15/08/72	NONE		
US-A- 4419094	06/12/83	CA-A-	1171336	24/07/84
		DE-A,C-	3214905	23/12/82
		US-A-	4867745	19/09/89
US-A- 4767411	30/08/88	DE-A-	3879954	06/05/93
		EP-A,B-	0381673	16/08/90